

### **Remarks**

The following is a response to the Office Action dated July 14, 2005 and subsequent to the interview held between the examiner and the undersigned on October 5, 2005.

The undersigned hereby expresses his appreciation to the examiner for the courtesy the examiner extended during the aforementioned interview.

Claims 10-16 and 18-25 were objected to due to alleged means-plus-function language.

To overcome this rejection, the "collar reception means" limitation has been changed to "collar reception mechanism". With this amendment, it is respectfully submitted that whether "collar reception means" is indeed means-plus-function language is now moot.

Claims 10-12, 15, 18-20 and 23 were rejected under 35 U.S.C. 102(b) as being anticipated by Burns (US 5,634,219); claims 14, 22 and 25 were rejected under 35 U.S.C. 103 as being obvious over Burns; and claims 13, 16, 22 and 24 were rejected under 35 U.S.C. 103 as being obvious over Burns in combination with Guyre et al. (US 5,681,295).

During the interview, the examiner agreed that the 35 U.S.C. 102(b) rejection may be overcome if the claims were amended to recite that the syringe is a unitary molded syringe, instead of the two-piece structure of the needle assembly 10b and the syringe 37 shown in Fig. 11 of Burns.

Per the above-amendment, claims 10 and 18 each have been amended to recite that the at issue syringe is a one-piece unitary molded syringe that includes a needle hub that has extending therefrom a fixed needle. The support for the amendment is provided, for example, by Figures 1, 6 and 7 of the drawings. With such recitation, it is believed that the anticipation rejection is no longer sustainable.

During the interview, the examiner also commented that even were the anticipation rejection overcome, he would render an obviousness rejection against the same claims under Burns.

In anticipation of this potential section 103 rejection, submitted with this amendment is a Declaration by Mr. Frederick Zecha, who attests to the commercial success, and to a lesser extent the long felt need, of the claimed invention, which is being sold as the Fixed Needle Syringe described in Appendix A of the Declaration. The actual Fixed Needle Syringe product was shown to the examiner during the aforementioned interview..

As evidenced by the Declaration, it is respectfully submitted that it is not obvious that the different elements of the Fig. 11 embodiment of Burns may be combined as suggested by the examiner, for products having separate non-fixed needle assemblies and syringes were in fact marketed by a number of companies, including the assignee of the instant invention prior to the instant invention. Yet when it was introduced, without any major advertising or promotion, a significant share of the competitive syringe market was gained by the Fixed Needle Syringe covered by the instant invention. And from the sales figures provided in the declaration, it is apparent that the Fixed Needle Syringe is a commercially successful product in that it had substantial sales in its first year, and that its sales more than double from its introduction year (2003) to 2004.

As was mentioned during the interview, injection syringes are products that are in a very crowded field. Yet prior to the instant invention, none of the myriad competitors of injection syringes (whose engineers obviously are persons skilled in the art) had thought of marketing a unitary molded syringe with a rotatable needle protective housing as claimed in the instant application. Thus, if anything, this lack of such "obvious" <sup>1</sup> product,

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<sup>1</sup> Although not shown on the front page, the assignee of the Burns patent (US 5643219), the reference relied upon by the examiner in the Office Action, is the Becton Dickinson Company, a major competitor in the syringe needle field. If the claimed invention was as obvious as the examiner asserted it to be, then Becton Dickinson clearly would have attempted to patent such device at the same time that they filed the Burns application (or at least include the claimed invention as an embodiment of the Burns disclosure), or would have introduced such product. Yet they did none of that.

coupled with the commercial success that the Fixed Needle Syringe has attained since its introduction, clearly rebut any assertion that the claimed invention is obvious over the prior art.

In view of the foregoing, it is respectfully submitted that the claimed invention is not anticipated by, or obvious over, the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the pending claims to issue at an early date.

Respectfully submitted,



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